Notice of Allowability	Application No.	Applicant(s)	
	09/386,266	BRAYDEN, DAVID J.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicants' amendment filed 02/02/06*.

2. ☒ The allowed claim(s) ~~is~~/are *35, 36, 38-42, 45 and 47, now renumbered as claims 1, 2, 3-7, 8, 9 and 10 respectively*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

 * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

 Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

ATTACHMENT TO NOTICE OF ALLOWABILITY

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 02/02/06 in response to the non-final Office Action mailed 07/28/05. With this, Applicants have amended the specification and the claims.

Examiner's Amendment

2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. Jonathan Dermott in a telephonic interview on 15 February 2006.

Claims 35, 41 and 47 of this application have been amended as indicated below:

--Claim 35 (Currently amended). A method of inducing a T_H1 polarized immune response to at least one antigen comprising parenterally administering to a subject microparticles comprising said at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said biodegradable polymer comprises a copolymer of lactic acid and glycolic acid of enantiomers thereof, and wherein said microparticles are sized such that the average diameter of said microparticles is from 2.4 μm to 4.3 μm and at least 50% of the microparticles are less than 5 μm.--

--Claim 41 (Currently amended). A vaccine formulation for enhancing a T_H1 immune response to at least one antigen and adapted for parenteral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising said at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said biodegradable polymer comprises a copolymer of lactic acid and glycolic acid or enantiomers thereof, and wherein said microparticles are sized such that average diameter of said microparticles is from 2.4 μm to 4.3 μm and at least 50% of the microparticles are less than 5 μm.--

--Claim 47 (Currently amended). A vaccine formulation for enhancing a T_H1 immune response to at least one antigen and adapted for parenteral administration comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising at least 2

subpopulations of microparticles, each subpopulation comprising a different antigen, each antigen entrapped or encapsulated by a biodegradable polymer, comprises a copolymer of lactic acid and glycolic acid of enantiomers thereof, and wherein said microparticles are sized such that the average diameter of said microparticles is from 2.4 μm to 4.3 μm and at least 50% of the microparticles are less than 5 μm.—

(b) At lines 3 and 4 of page 14 of the specification, the limitation 'Tween 20' has been replaced with --TWEEN 20--.

Status of Claims

3) Claims 37, 43 and 46 have been canceled via the amendment filed 02/02/06.

Claims 35, 41, 42 and 47 have been amended via the amendment filed 02/02/06.

Claims 35, 36, 39-42, 44, 45 and 47 are pending and are under examination.

Objection(s) Moot

4) The objection to claim 46 made in paragraph 19 of the Office Action mailed 07/28/05 is moot in light of Applicants' cancellation of claim 46.

Objection(s) Withdrawn

5) The objection to claim 47 made in paragraph 19 of the Office Action mailed 07/28/05 is withdrawn in light of Applicants' cancellation of the duplicative claim 46.

Rejection(s) Moot

6) The rejection of claim 46 made in paragraph 16 of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

7) The rejection of claim 46 made in paragraph 17 of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

8) The rejection of claim 46 made in paragraph 18(a) of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

9) The rejection of claim 46 made in paragraph 18(c) of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants'

cancellation of the claim.

10) The rejection of claims 43 and 46 made in paragraph 18(d) of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

11) The rejection of claim 47 made in paragraph 16 of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claims 35, 41, 47 and those dependent therefrom made in paragraph 17 of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the base claim.

13) The rejection of claims 35, 41 and 47 made in paragraph 18(a) of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

14) The rejection of claim 42 made in paragraph 18(b) of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claims 35, 41 and 47 made in paragraph 18(c) of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claims.

16) The rejection of claims 36-40, 42, 44 and 45 made in paragraph 18(d) of the Office Action mailed 07/28/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the base claim.

Remarks

17) Claims 35, 36, 38-42, 44, 45 and 47, now renumbered as claims 1, 2, 3-7, 8, 9 and 10 respectively, are allowed.

The descriptive support for the limitations added to claims 35, 41 and 47 via this Examiner's amendment is found in Examples 2, 3 and 7; third full paragraph on page 5; and page 6 of the

instant specification, as originally filed.

18) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax number for submission of amendments, responses and papers is (571) 273-8300.

19) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

February, 2006

S. DEVI, PH.D.
PRIMARY EXAMINER